Application No. 09/560,597
Filed: April 28, 2000
Group Art Unit: 3626

REMARKS

This Response is filed responsive to the Final Office Action dated February 27, 2003. All rejections and objections of the Examiner are respectfully traversed. Reconsideration is respectfully requested.

At paragraphs 2 and 3 of the Office Action, the Examiner rejected claims 1-14, 16-18, 20-25 and 28-38 under as being obvious under 35 U.S.C. 103, citing United States patent number 5,991,731 of Colon et al. ("Colon et al.") and an article by David I. Hopp entitled "Three Topics Integral to the use of the Internet for Clinical Trials: Connectivity, Communication, and Security" ("Hopp"). Applicants respectfully traverse this rejection.

Enclosed herewith is a revised Declaration under 37 C.F.R. 1.131, establishing a date of invention at least as early as August 31, 1998. The revised Declaration is respectfully believed to demonstrate evidence of the possession of the claimed invention by the inventors as of August 31, 1998, including the requisite means and their interaction. Examples of sections in the Grant Application (Exhibit A) specifically including support for establishment of the date of conception are referred to and described in the body of the Declaration. Moreover, the diligence of the inventors in pursuing the invention during the critical period is also described in the revised Declaration, with

reference to additional Exhibits B-M provided to support the description.

Based on this revised Declaration and the additional Exhibits included therein, Applicants respectfully urge that Hopp should not be considered prior art with regard to the present application. Since the teachings of Hopp regarding using the Internet for clinical trials and sharing documents with participants over the Internet are not disclosed or suggested in Colon et al., Applicants respectfully urge that no *prima facie* case of obviousness under 35 U.S.C. 103 is present with regard to independent claims 1, 8 and 29 when Hopp is not considered prior art. With regard to dependent claims 2-7, 9-25, 28 and 30-38, they each depend from one of independent claims 1, 8 or 29, and are respectfully believed to be patentable for at least the same reasons.

Alternatively, Applicants respectfully urge that even if Hopp is considered prior art, then the combination of Colon et al. and Hopp does not disclose or suggest all the elements of the present independent claims 1, 8 and 29. Specifically, nowhere in the *combination* of Colon et al. and Hopp is there disclosed or suggested any system or method of conducting a clinical trial of a test substance over the internet from a primary site, which includes ***assigning a unique identifier and a unique log-in***

*password to at least one clinical trial participant located at a remote internet site, the unique identifier and the unique log-in password for accessing protected information from the primary site*, where both the *providing to the participant of instructions on using the test substance, accessing and completing* at *least one evaluation form from a website maintained at the primary site, and returning electronically said at least one evaluation form to the primary site, and the providing of at least one evaluation form in electronic format for use by the participant, are responsive to receipt by the primary site of the unique identifier and said unique log-in password*, as in the present independent claims 1, 8 and 29.

In contrast, Colon et al. describe a system in which security measures are only considered for site investigators, regional directors, and study investigators. This reflects the objective of Colon et al. to provide a system for use at clinical sites by clinicians and other clinic employees. Accordingly, Colon et al. only describe using passwords with regard to protecting test results and other information entered into the system regarding the participants. There is no disclosure in Colon et al. of even the desirability of password protection provided on a per participant basis, in order to potentially control access to information in the instructions and/or evaluation forms, as in the

present independent claims 1, 8 and 29. Combining Hopp with Colon et al. does not cure this deficiency, since Hopp, even if it were to be considered prior art, only addresses the danger of interception of data between the remote and the central management sites. Hopp, therefore, only describes use of a virtual private network, based on encryption, as a solution to such security problems.

Accordingly, Applicants respectfully submit that even if Hopp is considered prior art, the combination of Colon et al. and Hopp fails to provide a *prima facie* case of obviousness under 35 U.S.C. 103. As to claims 2-7, 9-25, 28 and 30-38, they each depend from one of claims 1, 8 and 29, and are respectfully believed to be patentable over the combination of Colon et al. and Hopp for at least the same reasons.

At paragraph 4 of the Office Action, the Examiner rejected claims 26 and 27 as being obvious under 35 U.S.C. 103, again citing Colon et al. and Hopp, as well as "Lily warns Nutri System about using Prozac", by Dinah Brin ("Brin"). As in the previous Amendment, Applicants respectfully traverse this rejection.

Brin is an article reporting that while there has been some marketing of a drug combination including Prozac by a company specializing in weight loss products, the use of Prozac in such a combination is not endorsed by the maker of Prozac, and may have

adverse side effects. The disclosures of Colon et al. and Hopp are discussed above with respect to the rejections in paragraphs 2 and 3 of the Office Action.

Applicants again respectfully submit that Hopp should not be considered prior art, based on the enclosed revised Declaration under 37 C.F.R. 1.131, establishing a date of invention prior to Hopp. Moreover, Applicants urge that even were Hopp to be considered prior art, nowhere in the combination of Colon et al., Hopp and Brin is there disclosed or suggested any system or method of conducting a clinical trial of a test substance over the internet from a primary site, which includes ***assigning a unique identifier and a unique log-in password to at least one clinical trial participant located at a remote internet site, the unique identifier and the unique log-in password for accessing protected information from the primary site,*** where both the ***providing to the participant of instructions on using the test substance, accessing and completing at least one evaluation form from a website maintained at the primary site, and returning electronically said at least one evaluation form to the primary site, and the providing of at least one evaluation form in electronic format for use by the participant, are responsive to receipt by the primary site of the unique identifier and said unique log-in password,*** as in the present independent claims 1 and 8, from which claims 26

and 27 depend. Accordingly, Applicants respectfully urge that the combination of Colon et al., Hopp and Brin does not disclose or suggest all the elements of the present independent claims 1 and 8, from which claims 26 and 27 depend. The combination of Colon et al., Hopp and Brin therefore fails to provide a *prima facie* case of obviousness under 35 U.S.C. 103 for claims 1 and 8. Claims 26 and 27, which depend from claims 1 and 8, are respectfully believed to be patentable over the combination of Colon et al., Hopp and Brin for at least the same reasons. Reconsideration of all pending claims is respectfully requested.

As all claims are believed to be allowable, the application is believed to be in condition for allowance. Favorable action is respectfully requested.

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The Examiner is encouraged to telephone the undersigned attorney to discuss any matter that would expedite allowance of the present application.

Respectfully submitted,

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